

Applicant has amended Claims 1 and 5 to eliminate the double recitation of the phrase "one or more components selected from the group consisting of octadecanol, eicosanol, docosanol, tetracosanol and hexacosanol."

Applicant respectfully submits that the cited references do not singularly or in combination teach, suggest or anticipate the present invention. The present invention teaches compositions comprising "wood alcohols" of the composition indicated on Table I (set forth below) or a mixture of said "wood alcohols" and one or more components selected from the group consisting of beta-sitosterol, beta-sitostanol, campesterol, campestanol, stigmasterol, stigmastanol or a fatty acyl esters of said sterols and stanols, said compositions being useful blood cholesterol lowering agents. The Sorkin ('393) reference discloses compositions for reducing serum cholesterol levels comprising rice bran wax (a mixture of policosanols, whose composition is shown on Table I below) and phytosterols or plant sterols.

Applicant respectfully submits that there are at least two striking and fundamental differences between the claims of this application and Sorkin: 1) substantial differences in composition of the mixture of policosanols; 2) claims of this application include the utilization of stanols. There are significant differences in composition between wood alcohols and plant wax alcohols as shown in the following Table.

TABLE I:

**RANGE OF COMPOSITIONS IN WEIGHT % OF
POLICOSANOLS FROM DIFFERENT SOURCES**

Alypathic Alcohols Name (Number) of carbon atoms in molecule	Plant Wax Alcohols			Wood Alcohols Present Invention	
	Sugarcane Wax US Pat. No. 5,856,316	Ricebran Wax US Pat. No. 5,952,393	Beeswax US Pat. No. 6,225,354	Tall Oil Pitch	Tall Oil Soap
Octadecanol (18)	0	0	0	0	1-10

Eicosanol (20)	0	0	0	1-5	5-25
Docosanol (22)	0	1-1.6	0	5-30	20-60
Tetracosanol (24)	0.5-1	9.7-14	1-4	20-60	20-50
Hexacosanol (26)	5.5-8.5	8.9-12.7	7-12	15-50	1-5
Heptacosanol (27)	2-3.5	0	1-4	0	0
Octacosanol (28)	60-70	16.9-24.3	30-60	0	0
Nonacosanol (29)	0.4-1.2	0	2-5	0	0
Triaccontanol (30)	10-15	25.3-36.3	16-26	0	0
Dotriaccontanol (32)	4-6	14.1-20.2	13-22	0	0
Tetratriacontanol (34)	0.4-2	6.7-9.6	2-6	0	0
Hexatriacontanol (36)	0	1.5-2.2	0	0	0

The present application claims the utilization of stanols, where stanols are *not found* in plant sterols derived from any vegetable oil. Sorkin discloses the use of phytosterols “occurring in many common vegetable food products.” Wood sterols contain stanols which do not occur in vegetable food products. As such, it is Applicant’s believe that Sorkin does not anticipate the present invention.

The Examiner also relies on Sorkin (‘393), Maurel et al (‘924) and Perez (‘354). Applicant respectfully submits that Maurel et al teaches the preparation of an organometallic complex with either sitosterol or sitostanol and a method for the treatment or prevention of several diseases, including hypercholesterolaemia and hypertriglyceridaemia, and as such, does not bear reference to the field of invention of either the present invention or the other patents.

Sorkin (‘393), Perez (‘354) disclose compositions derived from plant waxes, and their use as blood cholesterol lowering agents. The present invention is distinguishable from these references. There are striking differences in composition between wood alcohols and plant wax alcohols like those shown in Table I. Policosanols comprise a wide array of organic compounds characterized by the presence of a single hydroxy functional group, generally but not exclusively, understood as long chain alypathic alcohols without specifying as to what is meant

by "long chain" and whether these chains are only linear or could be also branched. It is known in the art that the physiological and/or biochemical effects of chemical compounds can not be predicted from its structure, and even minor changes in structure may bring about dramatic changes in their pharmacological effects. For example, the utilization of policosanol docosanol, which was recently approved by the FDA as an antiviral agent for topical use, where the policosanol tetracosanol with only two additional carbon atoms per molecule does not possess antiviral activity. It is Applicant's belief that the above considerations are applicable for the determination of overcoming obviousness for the instant invention.

In terms of the provisional double-patenting rejection, Applicant respectfully request that a determination be made on the merits of the present invention, as well as on 09/772,790, after which Applicant will, if necessary, make a terminal disclaimer.

It is Applicant's belief that this application is in a condition for allowance. An action so indicating is respectfully requested. If the Examiner believes that discussion of this application would be beneficial, the undersigned may be contacted at the telephone numbers indicated below.

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It is Applicant's understanding that a three month extension of time is due for the submission of this *Amendment*. Please see the enclosed *Request for Extension of Time*, which authorizes a deduction of the required fee from Deposit Account 02-0400 (Baker & McKenzie).

May 27, 2003

Respectfully submitted,

A handwritten signature in black ink, appearing to read "David I. Roche". The signature is fluid and cursive, with the first name "David" and last name "Roche" clearly distinguishable.

David I. Roche
Reg. No. 30,797

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